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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,667	09/09/2003	Gary A. Koppel	22064-69748	3630

23643 7590 11/29/2006

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EXAMINER	
RAE, CHARLESWORTH E	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/658,667	KOPPEL, GARY A.	
	Examiner	Art Unit	
	Charleswort Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/21/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-32, 62-64, 78, 80-83, and 90-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *18-32, 62-64, 78, 80-83, and 90-91* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 18-32, 62-64, 78, 80-83, and 90-91 are currently pending and are the subject of this Office Action. Claims 1-17, 33-61, 65-77, 79 and 84-89 were canceled in the Preliminary Amendment filed 09/09/03.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 18-32, drawn to a method of enhancing cognitive function in a warm-blooded vertebrae comprising the step of administering an effective amount of a compound capable of inhibiting the peptidase activity of one or more neurogenic peptidases in the brain, classified in class 514, subclass 13+, 193, 200+.

II. Claims 62-64, drawn to a method of treating cognitive disorders in a warm-blooded vertebrae comprising the step of inhibiting neurogenic peptidase inhibition in the brain with effective amounts of the peptide Ala-D-γ-Glu-Lys-D-Ala-D-Ala, classified in class 514, subclass 23+.

III. Claims 78, 80, 81, 82, 83, 90-91, drawn to the method of using in the manufacturing of a medicament an inhibitor of the peptidase activity of a N-acetylated-α-linked-acidic dipeptidase as the active ingredient in a cognition enhancing composition in mixture with a pharmaceutically acceptable carrier, classified in class 514, subclass 13+.

IV. Claims 78-83, 90-91, drawn to the use, in the manufacture of a medicament, of an inhibitor of the peptidase activity N-acetylated-α-linked-acidic dipeptidase as the active ingredient

Inventions I, II, and III are directed to related methods of inhibiting peptidase activity. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct because the inventions are either not capable of use together or can have a materially different design, mode of operation, function in view of their divergent subject matter. Specifically, Invention I is drawn to a method of enhancing cognitive function in a warm-blooded vertebrae; Invention II is directed towards to a method of treating cognitive disorders in a warm-blooded vertebrae; Invention III is directed towards a method of using in the manufacturing of a medicament an inhibitor of the peptidase acitivty of a N-acetylated-α-linked-acidic dipeptidase as the active ingredient in a cognition enhancing composition in mixture with a pharmaceutically acceptable carrier. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Invention IV encompasses "use claims" that may be construed to be either product or process claims. Invention III encompasses these said "use claims." For purposes of restriction, the claims of invention III are being interpreted as product claims

for Group IV. Inventions IV and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the inventions as claimed are distinct because the product as claimed can be used in a materially different process of using that product. Specifically, invention IV may be used in a materially different process of treating prostate cancer.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Election of Species regarding Groups I-IV

This application contains claims directed to more than one species of the generic Inventions that would require an unduly extensive and burdensome search by the examiner if all the claimed species were examined together.

For example, inventions I-IV encompass multiple species of compounds capable of inhibiting peptidase activity of one or more neurogenic peptidases in the brain; namely,

a) β-lactam compounds, including: 1) penicillins, 2) cephalosprorins, 3) penems, 4) 1-oxa-1-dethia cephems, 5) clavams, 6) azetidinones, 7) carbapenams, 8) carbacephems, 9) 1-oxa-1-dethia-analogue of a cephalosporin, 10) 2-optionally

substituted oxa-2-deamino analogue of glutamic acid, 11) 2-optionally substituted carba-2-deamino analogue of glutamic acid, 12) N-substituted derivative of glutamic acid, 13) compound of general formula as claimed in claim 28

b) P-glycoprotein efflux pump inhibitor,

c) compound of general formula as claimed in claims 14 and 28, including: 1) moxalactam, or 2) flomoxef.

Applicant is required to elect one specifically defined exact compound capable of inhibiting peptidase activity from one of the above lists (a-c), e.g. c1 = moxalactam, for purposes of examination.

If a compound of the general formula as claimed in claim 28 is elected, then the elected compound must have an exact chemical structure wherein, R, R1, T, B, H are specifically defined.

These species are independent or distinct because they represent different chemical compounds and have acquired a different status in the art. In view of the undue search burden that will be created by the multiple species encompassed by these claims, applicant is required to elect one exact specific compound for examination purposes and provide justification for the election with respect to differences in structure, function, and method of using as appropriate.

Additional Election of Species regarding Groups I, II, III, & IV

Also, inventions I-IV encompass multiple species of different disorders that constitute independent or distinct species based on diagnostic and clinical features. For example, the following represent different diagnostic species:

a) dementia, b) amnesia, and c) Alzheimer's Disease.

The species are independent or distinct because they represent different diagnostic disorders. In view of the fact that the different diagnostic disorders have acquired a different status in the art, coupled with the divergent subject matter, an undue search burden will be created if all of the species were to be examined together. Thus, applicant is required to elect one specific disease state from the above list for examination purposes.

Additional Election of Species regarding Groups I-IV

Inventions I-~~IV~~ encompass multiple species of warm-blooded vertebrae, including: human, canine, feline, and equine. These species are independent or distinct because of their different genetic characteristics. In view of the different genetic characteristics of the species, an undue search burden will be created if all of the species were to be examined together. Thus, applicant is required to elect one single species for purposes of examination e.g. human, or canine, or feline, or equine.

Additional Election of Species regarding Groups I-IV

Inventions I-~~IV~~ encompass multiple species of subcombinations pharmaceutical formulations/medicament which exhibit different pharmaceutical properties resulting in different pharmacokinetic profiles. To the extent that the pharmacokinetic profiles of the pharmaceutical formulations are different, the species constitute independent or distinct pharmaceutical dosage formulations. For example, a) immediate release oral dosage formulation, or b) immediate release parenteral dosage formulation, or c) prolonged release oral dosage formulation, or

d) prolonged release parenteral dosage formulation, represent different pharmaceutical formulations.

Applicant is required to elect one exact pharmaceutical formulation for examination purposes (e.g. a, or b, or c, or d) wherein the each active ingredient(s), pharmaceutical carrier(s), and amounts of each ingredient(s), as well as the corresponding effective dosage (μg/kg of patient body weight) of the pharmaceutical formulation, are specifically defined.

Under 35 U.S.C. 121, applicant is required to elect a single disclosed subcombination of a pharmaceutical formulation/medicament for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 18, 62, and 78 are considered generic to the above listed species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

13 November 2006
CER

11/25/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER